REMARKS

Claims 1, 2, 24, 31, 38, 64, and 65 are pending and are rejected.

The Examiner states that Applicant's March 17, 2008 Amendment has not been entered "since new language in the proposed amendment requires extensive consultation of the specification to confirm support of the new language. Furthermore, the amendment would require a new search since the claims previously did not require that the formulation is applied directly or indirectly."

Referring to the Advisory Action at p. 2 ¶3 (Rejection under 35 U.S.C. 112, first paragraph), it is the Examiner's position that there is no teaching that the time period of each application is "about three minutes each."

Applicant respectfully disagrees. Applicant discloses

> The duration and timing of treatment intervals and enzyme concentration in the composition can vary. Variables include the extent and type of lesion, the physical properties of the lesion, how long it takes for the lesion to be no longer visible, physician and patient preference, patient compliance, etc. As one example, a thick scaly lesion such as a verruca (wart) may require prolonged or repeated treatment relative to a flat non-scaly lesion. As another example, a physician administering the inventive composition may prefer a single treatment of a more concentrated dose than multiple treatments of less concentrated doses.
>
> The treatment regimen may also vary, and the treatment time may be extended or shortened by varying the enzyme concentration and the formulation of the composition (e.g., a single application in contact with the lesion for fifteen minutes, or three applications in contact with the lesion for five minutes each). <u>The treatment method may require short time intervals</u> where the lesion, such as icthyosis, actinic keratosis, and the like, is located primarily in the epidermis, the outermost layer of skin. <u>Longer times</u>, and higher enzyme concentrations, are necessary to treat lesions such as cysts, connective tissue disorders and the like, which are located in the deeper layers of the skin and thus require the enzyme to penetrate deeper through a greater volume of tissue.

Applicant's specification at p. 20 line 18 to p. 21 line 12.

Applicant respectfully asserts that the term "about" is supported in the specification, specifically, "The treatment method may require short time intervals" and "Longer times, and higher enzyme concentrations, are necessary to treat lesions such as cysts,…." Further, a person of ordinary skill in the art would know that a shorter time would include, for example, two minutes, two and half minutes, etc., or a longer time would include, for example, three and half minutes, four minutes etc, which may be necessary for treatment of the lesion as indicated above. For at least these reasons Applicant respectfully requests that the rejection be withdrawn.

Referring to the Advisory Action at p. 2 last ¶ continued on the top of p. 3 (Rejections under 35 U.S.C. 103), the Examiner states "In example 2 of SU 1685448, though regression of swelling was found with an increased amount of theophylline, it is also noted that the amount of trypsin had also

been increased. Thus, it is not clear that the swelling regressed only because the amount of theophylline was substantially increased. Further still, as swelling is regressed, there is indeed regulation of removal (decrease) of the seborrheic keratosis condition. There is no recitation in the claims that the lesion itself is removed."

Applicant respectfully disagrees. In addition to Applicant's arguments in his March 17, 2008 Amendment, Applicant respectfully reasserts that the amount of theophylline in SU 1685448's composition was increased more that 10 fold (16 g to 176 g), which corresponds to a 1,000% increase over the initial amount. In addition, the amount of trypsin in the composition was increased only 1.25 fold (0.04 g to 0.05 g, which corresponds to a 25% increase over the initial amount). Applicant reasserts that a person of ordinary skill in the art would not predict any connection between removal of the swelling, and removal of the lesion. In addition, it is unclear if the reduction of swelling is actually due to the action of theophylline on the irritation produced by DMSO; DMSO causes extreme skin irritation as provided by Zaias.

Further, in reference to the Examiner's assertion that "there is no recitation in the claims that the lesion itself is removed", Applicant has amended claims 1, 24, and 64 to recite that the condition is removed. This is supported at least in Example 1, line 11, specifically, "the lesion was completely eliminated", thus introducing no new matter.

Referring to Advisory Action p. 3 ¶1 beginning with "With respect to the teaching of occlusion for therapy in SU 1685448, it is the Examiner's position that the claims recite "comprising" steps, and does not exclude other steps, including the presence of an occlusive dressing as taught in SU 1685448. "The instant claims do not recite that the physiologically acceptable formulation cannot be applied along with an occlusive dressing."

Applicant amended claims in his March 17, 2008 Amendment last ¶ p. 4 to top of p. 5, to recite that the application may be direct or indirect. Examples of indirect application include bandage, dressing, or covering, supported at least in FIGS. 1-4 and at p. 20 lines 13-17. In addition to the arguments provided in Applicant's March 17, 2008 Amendment regarding enhancement of skin hydration by occlusion, Applicant provides additional examples of indirect application which include pads, plasters, strips, gauze, sponge materials, cotton wool pieces, etc., these are indirect applications that are not occlusive, as well as occlusive dressings, supported in U.S. Patent No. 5,981,256, which is incorporated by reference, at col. 17 line 64 to col. 18 line 9. Applicant respectfully reasserts that a person of ordinary skill in the art would be taught that increased skin hydration, as a result of occluding the affected skin area, is required for treating seborrheic keratosis based on the teachings of SU 1685448.

Hence, Applicant has amended claims 1, 24, and 64 to recite that the indirect application is not occlusive. Applicant respectfully asserts that recitation of the term "comprising" is appropriate.

In reference to the secondary Zaias and Rawlings references, Advisory Action p. 3 ¶2, the Examiner provided these to demonstrate that DMSO causes skin irritation and is not needed for the application of trypsin to the skin. Applicant reasserts arguments in his March 17, 2008 Amendment that

Zaias does not provide a teaching for removing skin lesions with trypsin, and Rawlings does not teach treating seborrheic keratosis.

In reference to the secondary Burbach reference, Advisory Action p. 3 ¶3, the Examiner's position is "the formation of lesions does not teach away from the clinical invention since Burbach uses different concentrations from the claimed invention." Applicant reasserts arguments in his March 17, 2008 Amendment that Burbach teaches away because Burbach's use of trypsin is to form a blister, not to treat a skin lesion.

Applicant asserts that the above reasons, and those in Applicant's March 17, 2008 Amendment, overcome the rejections over SU 1685448 and the secondary references, and respectfully requests these rejections be withdrawn.

CONCLUSION

Fees for a three month extension and a Request for Continued Examination are authorized (see Electronic Fee Calculation sheet). No further fees are believed due but, if necessary, the Office is authorized to charge them to Deposit Account No. 20-0809.

The Examiner is invited to contact Applicant's undersigned representative with questions.

Respectfully submitted,

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